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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,695	03/29/2002	Dirk Gerrit Meuleman	0/97263 US	5130

7590 04/15/2004

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,695	MEULEMAN ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 30, 2003 has been entered.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 2 define R1 = H, OH or O. The use of H, OH is inconsistent with claim 1, which use the format H(OR3) for define the moieties attached at 3-position, and is confusing in that if the R1 equal to H and OH, or O; or R1 equal to H, OH, or O.

5. Claim 6 depends on a cancelled claim. The claim is indefinite as to the method claimed therein.

Claim Rejections 35 U.S.C. 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1617

7. Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Haenggi et al. (of record).

1. Haenggi et al. treated postmenopausal women with Tibolone with a daily amount of 2.5 mg (page 646, Patients and Methods), which meet the effective amount herein (see page 6, lines 25-30 herein in the specification). As to the functional limitation recited in the preamble herein, "inhibiting the atherosclerotic process," note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

Claim Rejections 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haenggi et al. (of record), in view of Berglund.

4. Haenggi et al. teaches a method of decreasing lipoprotein (a) by administering 7alpha-methyl-17alpha-ethynyl-17beta-hydroxy-5(10)-estren-3-one (Tibolone), to a human subject, see

Art Unit: 1617

the entire document, the abstract in particular. Haenggi further teaches that Lp(a) has been shown to be a strong independent risk factor for coronary disease, see the abstract.

5. Haenggi et al. does not teach expressly the employment of Tibolone in a method of inhibiting atherosclerosis.

6. However, Berglund teaches that Lp(a) has been implicated with an increased risk of atherosclerosis, see the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Tibolone in a method of inhibiting atherosclerosis.

A person of ordinary skill in the art would have been motivated employ Tibolone in a method of inhibiting atherosclerosis because Lp(a) has been implicated an increased risk of atherosclerosis.

Response to the Arguments

Applicants' remarks submitted December 30, 2003 have been fully considered, but are not persuasive.

Applicants argue that the instant claims are not obvious over Haenggi et al. because it is known that Tibolone also decrease the HDL-cholesterol. The arguments are improper. Particularly, the cited prior arts established that Lp(a) is closely associated with atherosclerosis, therefore, decrease of Lp(a) would have been reasonably expected to suppress, or inhibit the development of atherosclerosis. Applicants argue that Tibolone decrease HDL-cholesterol, however, fails to establish the relationship of the decrease of HDL-cholesterol and atherosclerosis. Applicants fails to establish a prima facie case that decrease of HDL-cholesterol

Art Unit: 1617

would have discourage one of ordinary skill in the art from using Tibolone for inhibiting atherosclerosis. Further, even if it is known that decrease of HDL-cholesterol is associated with atherosclerosis, there is no sufficient evidence to show that the decrease of HDL-cholesterol would out weight the benefit of lowing Lp(a), particularly, in view the fact that Lp(a) has been shown to be a strong independent risk factor for coronary heart disease.

7. Applicants contend that the instant claims are based on the discovery of unexpected benefit resided in the claims. The arguments are not persuasive. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). The claims are directed to mammal in general, and in human in particular. The data is based on rabbit, which, applicants admitted, is different from other mammal, such as human (Lp(a) not present, page 6 of the response). There is no reasonable expectation that such unexpected result would be extrapolated to other mammal. Therefore, the unexpected results are not commensurate with the scope herein claimed. Further, note the claims have also been anticipated. See the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Application/Control Number: 09/380,695

Page 6

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

 **SHENGJUN WANG
PRIMARY EXAMINER**

Shengjun Wang

April 12, 2004